1635

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	LI et al.	Group Art Unit:	1635
Serial No.:	10/038,984	Examiner:	: TRACY ANN VIVLEMORE
Filed:	JANUARY 4, 2002	Docket No.:	275.0003 0102
		Confirmation No.:	9705

Title: COMPOSITION AND METHOD FOR IN VIVO AND IN VITRO ATTENUATION OF GENE EXPRESSION USING DOUBLE STRANDED RNA

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CHARGE ALL FEES TO DEPOSIT ACCOUNT 13-4895

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

X **Small entity status is entitled to be asserted in the above-identified application.**
X **An itemized return postcard.**
__ A Petition for Extension of Time for _ month(s). Please charge Deposit Account No. 13-4895 in the amount of $_ for the required fee.
X **An Information Disclosure Statement (3 pgs); 1449 forms (31 pgs); and copies of 426 documents cited on the 1449 forms. Charge Deposit Account 13-4895 the amount of $180 to cover the required fee.**
__ A check in the amount of $_, representing ___.
__ Other: ___.
__ Amendment ___ No Additional fee is required. ___ The fee has been calculated as shown:

Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x $25 =	
Independent Claims				x $100 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add $180 Here →					
Total Additional Claim Fees Required					

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: **Mail Stop Amendment,** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 19 day of December, 2006.

MUETING, RAASCH & GEBHARDT, P.A.
Customer Number: 26813

By: David L. Provence
Name: David L. Provence
Reg. No.: 43,022
Direct Dial: 612-305-1005
Facsimile: 612-305-1228

PATENT
Docket No. 275.00030102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	LI et al.	Group Art Unit:	1635
Serial No.:	10/038,984	Examiner:	Tracy Ann Vivlemore
Confirmation No.:	9705		
Filed:	January 4, 2002		

For: COMPOSITION AND METHOD FOR IN VIVO AND IN VITRO ATTENUATION OF GENE EXPRESSION USING DOUBLE STRANDED RNA

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Pursuant to MPEP § 609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 form(s) is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Applicants would also like to bring to the Examiner's attention Benitec v. Nucleonics Civil Action No. 04-CV-0174 (JJF) in the U.S. District Court for the District of Delaware. Certain documents cited herein were first brought to the Applicants' attention in a search of literature related to this action.

Should the Examiner wish to review any documents in Applicants' possession related to this action, the Examiner is invited to contact the undersigned and any documents requested will be forwarded.

Documents U.S. Patent 5,578,716, WO 94/01550A1, Barlow et al., Beretta et al., Billy et al., Brand et al., Brummelkamp et al. (*Cancer Cell*, 2:243-247, (2002)), Burke et al., Haggarty et al., Harada et al., Kirchhoff et al., McManus et al. (*RNA*, 8:842-850 (2002)), Thoemis et al., listed on the attached Form PTO-1449 were cited in an Opposition of EP 1230375 B1.

Documents U.S. 5,631,148 (Urdea), and WO 99/32619 A1, of record, were also cited in the opposition.

Documents WO 95/27783 A1, WO 97/34638 A1, and Schaefer et al., listed on the attached Form PTO-1449 were cited in a foreign search or examination report corresponding to Korean application serial no. 10-2001-7013385 and mailed on August 8, 2006. This application has inventors in common with the instant application.

An English translation of non-English document, Zakharyan et al., is attached to the document. U.S. Patent 5,788,265 is being submitted as an English language equivalent of non-English document, EP 0 560 156 A2. An English abstract of non-English publications WO 92/19732 A1, WO 95/18223 A1, WO 98/05770 A2 and WO 00/44895 A1, may be found on the cover page of the publication. An English abstract of non-English publications JP 09-110894 A and JP 09-227413 may be found attached to the publication.

Since this Information Disclosure Statement is submitted after the receipt of an Office Action in the above-identified patent application, Applicants hereby authorize a charge of $180 to Deposit Account No. 13-4895 to cover the fee required under 37 C.F.R. §§1.97(c) and 1.17(p). Please charge any additional fees or credit any overpayment to Deposit Account No. 13-4895.

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450,

on this 19 day of Dec., 2006.

DaJL Provence

Name: David L. Provence

Respectfully submitted
By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612)305-1220
Facsimile: (612)305-1228
Customer Number 26813

December 19, 2006
Date

By: DaJL Provence
David L. Provence
Reg. No. 43,022
Direct Dial (612)305-1005

INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.*	PAGE 1 of 31
	Information Disclosure Statement Mailed :	December 19, 2006
	Filing Date: January 4, 2002	Group Art Unit: 1635

U.S. PATENT DOCUMENTS

Initial	Copy Enclosed	Document No.	Date	Name	Class	Sub-Class	Filing Date
		US 2002/0086356 A1	07/04/2002	Tuschl *et al.*			
		US 2002/0168707 A1	11/14/2002	Graham			
		US 2003/0018993 A1	01/23/2003	Gutterson *et al.*			
		US 2003/0036197 A1	02/20/2003	Glassman *et al.*			
		US 2003/0061626 A1	03/27/2003	Plaetinck *et al.*			
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		US 2003/0165894 A1	09/04/2003	Waterhouse *et al.*			
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		US 2004/0138168 A1	07/15/2004	Satishchandran *et al.*			
		US 2004/0180439 A1	09/16/2004	Graham *et al.*			
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		US 4,130,641	12/19/1978	Ts'o *et al.*			
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		US 5,365,015	11/15/1994	Grierson *et al.*			
		US 5,453,566	09/26/1995	Shewmaker *et al.*			
		US 5,514,546	05/07/1996	Kool			
		US 5,578,716	11/26/1996	Szyf *et al.*			
		US 5,643,762	07/01/1997	Ohshima *et al.*			
		US 5,683,985	11/04/1997	Chu *et al.*			

Examiner	Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 2 of 31	
	Filing Date: January 4, 2002	Group Art Unit: 1635

U.S. PATENT DOCUMENTS

Initial	Copy Enclosed	Document No.	Date	Name	Class	Sub-Class	Filing Date
		US 5,686,649	11/11/1997	Chua *et al.*			
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		US 5,693,773	12/02/1997	Kandimalla *et al.*			
		US 5,714,323	02/03/1998	Oshima *et al.*			
		US 5,739,309	04/14/1998	Dattagupta *et al.*			
		US 5,747,338	05/05/1998	Giese *et al.*			
		US 5,795,715	08/18/1998	Livache *et al.*			
		US 5,798,265	08/25/1998	Springer *et al.*			
		US 5,808,036	09/15/1998	Kool			
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		US 6,531,647	03/11/2003	Baulcombe *et al.*			
		US 6,635,805	10/21/2003	Baulcombe *et al.*			
		US 09/646,807	Not Published	Graham *et al.*			
		US 60/117,635	Not Published	Li *et al.*			
		US 60/130,377	Not Published	Pachuk *et al.*			

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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 3 of 31	
	Filing Date: January 4, 2002	Group Art Unit: 1635

FOREIGN PATENT DOCUMENTS

Initial	Copy Enclosed	Document No.	Date	Country	Class	Sub-Class	Translation
	X	AU 200195225 A1	01/31/2002	Australia			
	X	AU 729454	02/01/2001	Australia			
	X	AU 743316	01/24/2002	Australia			
	X	CA 2012312 C	09/16/1990	Canada			
	X	CA 2370628 A1	10/26/2000	Canada			
	X	DE 199 03 713.2	Not Published	Germany			
	X	EP 0 213 921 A2	03/11/1987	Europe			
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	X	EP 0 281 380 B1	11/29/1995	Europe			
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	X	EP 0 308 066 A2	03/22/1989	Europe			
	X	EP 0 308 066 A3	01/16/1991	Europe			
	X	EP 0 308 066 B1	12/27/1995	Europe			
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	X	EP 0 347 501 A1	12/27/1989	Europe			
	X	EP 0 350 151 A2	01/10/1990	Europe			
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	X	EP 0 350 151 B1	03/30/1994	Europe			
	X	EP 0 465 572 B1	06/14/1995	Europe			

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	Applicants: Li *et al.* PAGE 4 of 31	
	Filing Date: January 4, 2002	Group Art Unit: 1635

FOREIGN PATENT DOCUMENTS

Initial	Copy Enclosed	Document No.	Date	Country	Class	Sub-Class	Translation
	X	EP 0 560 156 A2	09/15/1993	Europe			No
	X	EP 0 921 195 A1	06/09/1999	Europe			
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	X	WO 92/19732 A1	11/12/1992	WIPO			No
	X	WO 93/17098 A1	09/02/1993	WIPO			
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Examiner	Date Considered

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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 5 of 31	
	Filing Date: January 4, 2002	Group Art Unit: 1635

FOREIGN PATENT DOCUMENTS

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	X	WO 03/027298 A1	04/03/2003	WIPO			
	X	WO 03/056012 A1	07/10/2003	WIPO			

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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 6 of 31	
	Filing Date: January 4, 2002	Group Art Unit: 1635

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

Initial	Copy Enclosed	
	X	"somatic cell," on-line medical dictionary, http://cancerweb.ncl.ac.uk/cgi-bin/ (January 2006).
	X	Agrawal *et al.*, "RNA Interference: Biology, Mechanism, and Applications" *Microb. Mot. Biol. Rev.* 67:657-685 (2003).
	X	Agrawal *et al.*, "Self-Stabilized Oligonucleotides as Novel Antisense Agents," in Delivery Strategies: antisense oligonucleotide therapeutics, Ahktar *et al.*, Eds., pp. 105-121 CRC Press, Inc., Boca Raton, Florida (1995).
	X	Agrawal, "Antisense oligonucleotides: towards clinical trials," *TIBTECH* 14: 376-387 (1996).
	X	Akgun *et al.*, "Palindrome Resolution and Recombination in the Mammalian Germ Line", *Mol. Cell. Biol.* 17: 5559-5570 (September 1997).
	X	Akhtar *et al.*, "Anti-HIV therapy with antisense oligonucleotides and ribozymes: realistic approaches or expensive myths?" *J. Antimicrob. Chemother.* 38: 159-165 (1996).
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	X	Anderson, "Human gene therapy," *Nature* 392:25-30 (1998).
	X	Annex A filed in EP 99 910 039.9.
	X	Annex B filed in EP 99 910 039.9 (September 9, 2005).
	X	Annex C filed in EP 99 910 039.9 (September 9, 2005).
	X	Annex D filed in EP 99 910 039.9 (September 9, 2005).
	X	Appeal against decision to refuse a European patent application issued July 11, 2005, filed in EP 99 910 039.9 (September 9, 2005).
	X	Assaad *et al.*, "Epigenetic repeat-induced gene silencing (RIGS) in *Arabidopsis*," *Plant Molecular Biology* 22(6): 1067-1085 (1993).

Examiner	Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 7 of 31	
	Filing Date: January 4, 2002	Group Art Unit: 1635

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

Initial	Copy Enclosed	
	X	Author unknown, "Breakthrough of the Year #4: Still hot," *Science* 302:2038-2045 (2003).
	X	Bahner *et al.*, "Transduction of Human CD34 $^{+}$ Hematopoietic Progenitor Cells by a Retroviral Vector Expressing an RRE Decoy Inhibits Human Immunodeficiency Virus Type I Replication in Myelomonocytic Cells Produced in Long-Term Culture," *J. Virol.* 70:4352-4360 (1996).
	X	Balandin *et al.*, "Silencing of a β-1-3-glucanase transgene is overcome during seed formation," *Plant Molecular Biology* 34(1):125-137 (1997).
	X	Barbeau *et al.*, "Characterization of the human and mouse Fli-1 promoter regions," *Biochim. Biophys. Acta* 1307: 220-232 (1996).
	X	Barlow *et al.*, "Interferon synthesis in the early post-implantation mouse embryo," *Differentiation* 27:229-235 (1984).
	X	Bass, "RNA Interference: The short answer," *Nature* 411:428-429 (2001).
	X	Baulcombe, "RNA as a target and an initiator of post-transcriptional gene silencing in transgenic plants," *Plant Molecular Biology* 32(1-2):79-88 (1996).
	X	Baum *et al.*,"Inhibition of Protein Synthesis in Reticulocyte Lysates by a Double-Stranded RNA Component in Hela mRNA," *Biochem. Biophys. Res. Commun* 114:41-49 (1983).
	X	Beretta *et al.*, "Expression of the protein kinase PKR is modulated by IRF-1 and is reduced in 5q- associated leukemias," *Oncogene* 12:1593-1596 (1996).
	X	Betz, "RNAi: RNA Interference," Promega Notes Magazine, Number 83, pp. 33-36 (2003).
	X	Bevec *et al.*, "Constitutive Expression of Chimeric *Neo*-Rev Response Element Transcripts Suppresses HIV-1 Replication in Human CD4^{+} T Lymphocytes," *Hum. Gene Ther.* 5:193-201 (1994).
	X	Bevilacqua, *et al.*, "Antisense RNA inhibits endogenous gene expression in mouse preimplantation embryos: Lack of double-stranded RNA "melting" activity," *Proc. Natl. Acad. Sci. USA* 85:831-835 (1988).
	X	Bhan *et al.*, "2',5'-Linked Oligo-3'-deoxyribonucleoside phosphorothiate chimeras: thermal stability and antisense inhibition of gene expression" *Nucl. Acids Res.* 1(16):3310-3317 (1997).

Examiner	Date Considered

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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 8 of 31	
	Filing Date: January 4, 2002	Group Art Unit: 1635

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

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	X	Bigler *et al.*, "Novel location and function of a thyroid hormone response element," *EMBO J.* 14:5710-5723 (1995).
	X	Billy *et al.* "Specific interference with gene expression induced by long, double stranded RNA in mouse embryonal teratocarcinoma cell lines," *Proc. Natl. Acad. Sci. USA* 98(25):14428-14433 (2001).
	X	Bingham, "Cosuppression Comes to the Animals," *Cell* 90(3):385-387 (1997).
	X	Birchler *et al.*, "Making noise about silence: repression of repeated genes in animals" *Curr. Opin. Genet. Develop.* 10:211-216 (2000).
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	Applicants: Li *et al.* PAGE 9 of 31	
	Filing Date: January 4, 2002	Group Art Unit: 1635

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	Applicants: Li *et al.* PAGE 10 of 31	
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	Applicants: Li *et al.* PAGE 11 of 31	
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	Applicants: Li *et al.* PAGE 12 of 31	
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	Applicants: Li *et al.* PAGE 13 of 31	
	Filing Date: January 4, 2002	Group Art Unit: 1635

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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 14 of 31	
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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 15 of 31	
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	Applicants: Li *et al.* PAGE 16 of 31	
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	Applicants: Li *et al.* PAGE 17 of 31	
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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 18 of 31	
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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 19 of 31	
	Filing Date: January 4, 2002	Group Art Unit: 1635

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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 20 of 31	
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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 21 of 31	
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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 22 of 31	
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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 23 of 31	
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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 24 of 31	
	Filing Date: January 4, 2002	Group Art Unit: 1635

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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 25 of 31	
	Filing Date: January 4, 2002	Group Art Unit: 1635

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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 26 of 31	
	Filing Date: January 4, 2002	Group Art Unit: 1635

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	Applicants: Li *et al.* PAGE 27 of 31	
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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) PTO Form 1449	Attorney Docket No. 275.00030102	Application No. 10/038,984
	Applicants: Li *et al.* PAGE 28 of 31	
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	Applicants: Li *et al.* PAGE 29 of 31	
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